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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,659	05/26/2006	Andrea Pastorello	50294/018001	5027

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EXAMINER	
KOSAR, AARON J	
ART UNIT	**PAPER NUMBER**
1651	

NOTIFICATION DATE	DELIVERY MODE
11/15/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/580,659	PASTORELLO ET AL.	
	Examiner	Art Unit	
	Aaron J. Kosar	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,19-61,63 and 75-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17, 19-61, 63, 75-82* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-49, 61, and 63 (in part) and claims 50-53, drawn to a multilayer composite material containing a pharmacologically/biologically active ingredient.

Group II, claims 1-49, 61, and 63 (in part) and claims 54-56, drawn to a multilayer composite material containing a loaded cell.

Group III, claims 57 (in part) and claim 58, drawn to fixing the matrix by heat-treating.

Group IV, claims 57 (in part) and claims 59-60, drawn to fixing the matrix by exposing the material to needle-punching/sewing.

Group V, claim(s) 75-79, drawn to a method comprising *implanting* a composition.

Group VI, claim(s) 80-81, drawn to a method comprising *fusing* adjacent bone and *forming* new bone.

Group VII, claim(s) 81, drawn to a method comprising *fusing* adjacent vertebral bodies.

Group VIII, claim(s) 82, drawn to a method comprising *filling* a vertebral body.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared or corresponding technical feature is a contribution over the prior art. Also, 37 CFR § 1.475 states,

> *(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.*
> *(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:*
> *(1) A product and a process specially adapted for the manufacture of said product; or*
> *(2) A product and process of use of said product; or*
> *(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or*
> *(4) A process and an apparatus or means specifically designed for carrying out the said process; or*
> *(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.*
> *(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.*
> *(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).*
> *(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.*

The inventions listed as Groups I-VIII do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature of Group I is a hyaluronic acid moiety and a matrix. PAVESIO (WO 02/070030 A1 (PTO-1449 5/26/2006)) teaches the technical feature of a hyaluronic acid moiety including a "matrix of

hyaluronic acid derivatives" with a "three-dimensional matrix". Thus the technical feature of the instant claims cannot be a *special technical feature*, because it does not make a contribution over the prior art, and unity of invention is lacking.

Applicant is required to elect a single invention group, indicating the claims that are included in the group, to which the claims shall be restricted. Please note, groups I-IV contain claims (claims 1-49, 61, and 63 or claim 57) which link the inventions (group I with II or III with IV). As such, if Applicant elects any one of groups I-IV above, the generic linking claims will be searched with the elected invention.

This application contains claims directed to more than one species of the generic invention.

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1. The species of material: *an ester of hyaluronic acid; an inner ester of hyaluronic acid with a percentage; an amide of hyaluronic acid; an O-sulphated derivative of hyaluronic acid; a deacetylated derivatives of hyaluronic acid; a percarboxylated derivatives of hyaluronic acid; and hyaluronic acid*
2. The species of matrix: *demineralised bone; biocompatible and biodegradable ceramic; bone; or a specific combination selected from the component species demineralised bone/bone/ceramic.*
    a. The subspecies of ceramic: *hydroxyapatite; tribasic calcium phosphate; and calcium sulphate.*
3. The species of polymer: *hyaluronic acid benzyl ester with a percentage of esterification of between 55 and 100%; fibrin glue; a photocrosslinkable polymer; collagen; and a derivative of collagen*
4. The species of pharmacologically active agent or biologically active agent: *an antibiotic, an antineoplastic, an anti-inflammatory, a cytokine, a vitamin, a cytotoxic agent , a cytostatic agent, an antiviral agent, a trophic factor, an osteoinductive factor, an angiogenetic factor, or a trophic, osteoinductive, angiogenetic factor.*
5. The species of loaded cells: *bone marrow cells; autologous and/or allogenic mesenchymal cells either undifferentiated or partially differentiated into osteoblasts; or autologous and/or allogenic mesenchymal cells that are completely differentiated into osteoblasts*

Applicant is required, in reply to this action, to elect a **single** species – that is, a single composition, *per se* or used in an elected method, clearly indicating the species comprising the components and the interrelation of the components therein - to which the claims shall be restricted if no generic claim is finally held to be allowable.

The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. If Applicant elects invention group I or II above, Applicant is required to elect a single species from each of species group (1)-(5) and (2)(a), above to the extent the species read upon the elected invention and to the extent the elected subspecies reads upon the elected species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: Currently, claim 1, 57, 75, 80, 81, and 82 are generics.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The claims lack a special technical feature as argued above. Also, the species do not relate to a general inventive concept, because the species are distinct chemical compositions with a myriad of potential substitutions which would require a distinct search of the prior art, including separate search strings. Furthermore, wherein the

substitutions of the various species may broadly and reasonably be interpreted as to include substitutions where the core structure of a hyaluronic acid moiety is not a significant portion of the total molecule/composition *and* the solubility, stability, reactivity, and other properties of each derivative/distinct composition would not be expected to be shared by all of the alternatives, and it would not be expected that members of each class (each species/combination of species) would behave in the same way in the context of the instantly claimed invention in all instances. Thus the claims lack a general inventive concept and restriction is deemed proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a single species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Rejoinder Practice

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so**

may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Joint Inventorship

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Kosar whose telephone number is (571) 270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron Kosar
Examiner, Art Unit 1651

SANDRA E. SAUCIER
PRIMARY EXAMINER